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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/841,609	04/25/2001	Vitaliy Arkadyevich Livshits	206339US0	4787
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WASHINGTON, DC 20036

EXAMINER

KERR, KATHLEEN M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/841,609

Applicant(s)

LIVSHITS ET AL.

Examiner

Kathleen M Kerr

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4, 7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/15/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

1. In response to the previous Office action, a non-final rejection (mailed on June 3, 2004), Applicants filed a response and amendment (received August 31, 2004). Said amendment amended Claim 4. Thus, Claims 4, 7 and 8 are pending in the instant Office action.

The Examiner notes that the listing of the pending claims filed August 31, 2004 has inappropriate status identifiers. Claim 5 should be noted as simply ---cancelled---; Claim 7 should be noted as ---previously presented---; and Claim 8 should be noted as ---withdrawn---. The following is recommended to clarify the rules for future prosecution: of 37 C.F.R. § 1.121, as amended on June 30, 2003 (see *68 Fed Reg. 38611*, June 30, 2003).

Election

2. Claims 4, 7, and 8 are pending in the instant application. Claim 8 is withdrawn from further consideration as a non-elected invention; Claim 8 is subject to rejoinder as a method of using the products in Claims 4 and 7. Claims 4 and 7 will be examined herein.

Priority

3. As previously noted, the instant application is granted the benefit of priority for the foreign application 2000110350 filed on April 26, 2000 in Russia. Said application is in English as noted by Applicants.

Information Disclosure Statement

4. The information disclosure statement filed on July 15, 2004 has been reviewed, and its references have been considered as shown by the Examiner's initials next to each citation on the attached copy. The "foreign document", an examination opinion written by EPO, has been considered but crossed through so as not to be printed on the face of the file since it is not a publication per se.

Withdrawn - Claim Rejections - 35 U.S.C. § 112

5. Previous rejection of Claims 4 and 7 under 35 U.S.C. § 112, second paragraph, as being indefinite for the term "*csc* genes originating from *Escherichia coli*" is withdrawn. By virtue of the amendment and Applicant's arguments, it is clear the intended genes are CscA (the invertase), CscK (the fructokinase), and CscB (the permease) as disclosed by Bockmann *et al.* (see page 7 of the specification).

6. Previous rejection of Claims 4 and 7 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicant's amendment. Not only are the claims clear, as noted above, but the claims are drawn to *E. coli* harboring specific genes from Bockmann *et al.* wherein the structures are specific and described.

7. Previous rejection of Claims 4 and 7 under 35 U.S.C. § 112, first paragraph, scope of enablement, is withdrawn by virtue of Applicant's amendment. Not only are the claims clear, as noted above, but the claims are drawn to *E. coli* harboring specific genes from Bockmann *et al.*

Art Unit: 1652

wherein the structures are specific and enabled since the exact sequences, to which the claims are limited, are known in the prior art.

Maintained - Claim Rejections - 35 U.S.C. § 102

8. Previous rejection of Claims 4 and 7 under 35 U.S.C. § 102(b) as being anticipated by Bockmann *et al.* is maintained. Applicant's arguments have been fully considered but are not deemed persuasive for the following reasons. Applicant argues that JM109 used by Bockmann *et al.* "does not have the ability to cause accumulation of an amino acid in a medium when the strain is cultured in the medium because the strain has not been bred to produce an L-amino acid." This argument is not found persuasive. No limitation of how much amino acid must be present to be considered "accumulated", thus, any production of amino acid can be considered to be accumulating. And it is well-known in the art that *E. coli* produces amino acids in the culture medium whether "bred" to do so or not; this breeding only enhances said production, but again, no limitation on the amount of accumulation is found in the claims or implied from the specification. As previously noted,

"Bockmann *et al.* teach *E. coli* JM109 harboring the expression plasmid pJMBL102, which contains the *csc* genes (see page 27, left column). Absent evidence to the contrary, such a transformant inherently accumulates amino acids in the media...

Applicant's own examples evidence this fact. On page 29 [of the instant specification], Table 4, *E. coli* strain 44-3-15 absent any *csc*-gene-containing plasmid produces isoleucine and on page 35, Table 7 *E. coli* strain SV164 absent any *csc*-gene-containing plasmid produces tryptophan.

Moreover, absent evidence to the contrary, the mere introduction of *csc* genes increases amino acid production in *E. coli*... **Applicant's own examples evidence this fact.** On page 29 [of the instant specification], Table 4, the mere introduction of *csc* genes into *E. coli* strain 44-3-15 produces an increase of isoleucine production of 0.1% (see glucose numbers; no limitation to amino acid production on sucrose is in the claims).

Thus, Bockmann *et al.* inherently teach the product claimed with all its limitations since said limitations are an inherent feature of the product explicitly taught by Bockmann *et al.*" (emphasis added)

Summary of Pending Issues

9. The following is a summary of the issues pending in the instant application:
- a) Claims 4 and 7 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Bockmann *et al.*

Conclusion

10. Claims 4 and 7 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

Art Unit: 1652

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

November 13, 2004